



# The Future of Gene Patenting and the Biotechnology Industry after Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al

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The Future of Gene Patenting and the Biotechnology Industry after *Association for*

*Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al*

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### Abstract:

The recent decision by Judge Sweet in *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al* has the potential to dramatically alter the landscape of pharmaceutical research in the United States. As more companies use genetic data and research to tailor drugs to specific individuals, gene patents have become a tool to insure long-term profitability. While the district court's decision will be tested on appeal, the industry must face the possibility that gene patents may be curtailed or even eliminated. Certainly biotechnology research will encounter greater public scrutiny as the case moves forward.

Pharmaceuticals are big business in the United States. Sales of brand and generic drugs in the United States reached \$ 274.7 billion in 2006.<sup>1</sup> The federal government and the public pay enormous amounts of money for medications, and the growing costs concern all levels of society. Part of this increased cost can be directly attributed to the increasing costs to develop new drugs. Drug research and development (R&D) is an expensive process. For drugs specifically, economists estimate that it takes twelve to fifteen years to develop a single new drug and have it approved by the Food and Drug Administration (FDA).<sup>2</sup> The average cost: \$ 800 million.<sup>3</sup> The ratio of researched products to usable products is staggering. For every 10,000 compounds investigated, only five are ever tested as potential medicines in clinical trials and only one is ever approved for patient use. Of all the drugs approved by the FDA, only three out of ten generate revenues that meet or exceed average research and development costs.<sup>4</sup>

The investments made into the industry have borne fruit: in 2005, pharmaceutical companies invested almost \$20 billion in R&D.<sup>5</sup> Since that investment, nearly 400 new products are either in the market or in development.<sup>6</sup> One of the pillars of current pharmaceutical research and development is gene patenting.<sup>7</sup> Without patent rights being secured, the Biotechnology Industry Organization (BIO) asserts the pharmaceutical development would be nearly impossible. Naturally BIO is at best a source predisposed to favor pharmaceutical companies, but it does raise the question of how changes to gene patenting will impact drug development in the United States.

As a general matter, the patent system is central to the biotechnology and pharmaceutical industries. Industries that do not advance rapidly, such as those dependent on the expensive drug development process, rely upon the full patent exclusivity period to recoup the discovery and development costs.<sup>8</sup> Furthermore, pharmaceutical innovators typically able to access only about half of the 20-year period of patent exclusivity due to the delay between needing patent protection and bringing the drug to the market.<sup>9</sup>

Drugs already being developed use the protection offered by gene patents--biopharmaceutical drugs ("biologics") currently make up 40% of all preclinical candidates and 25% of all new drug submissions for U.S. market approval.<sup>10</sup> Biologics are usually protected by gene patents.<sup>11</sup> Examples of biologics on the market include growth factors, monoclonal antibodies, hormones, cytokines, fusion proteins, blood factors, recombinant enzymes, recombinant vaccines, anticoagulants, and nucleic acids.<sup>12</sup> The variety of drug types is matched by the variety of diseases treated. Biologics are used to treat a variety of disorders such as cancer, AIDS, influenza, hepatitis, and diabetes.<sup>13</sup> Beyond the medical impact on individual consumers, biologics have been successful in the marketplace. In 2006, biologics brought in over \$30 billion in sales in the United States.<sup>14</sup> Biologics are expected to continue to have a significant role as drug therapies.<sup>15</sup>

With that incentive, it is unsurprising that gene patenting is extensive in the United States. In 2004, Murray and Jensen published a prominent article in the journal Science: they reported that the USPTO had issued 4,270 human gene patents for 4,382

distinct human genes. Based on this result, they determined that approximately one-fifth of known human genes were claimed in a U.S. patent.<sup>16</sup> Beyond human genes, there are approximately 20,000 patents covering a wide range of naturally occurring animal, plant, fungi and other DNA sequences.<sup>17</sup> Gene patents include “[n]ine patents [that] have been applied for on the genes which determine your eyeball, 40 on those for your heart, and no fewer than 152 on a single grain of rice.”<sup>18</sup>

However, scholars and practitioners often question the scope and validity of gene patents on the grounds that genes are so essential for any being and so important to basic research that it is unethical to grant a private monopoly on them. Moreover there are a limited number of genes found in nature- a creative researcher cannot simply invent new natural genes. Opponents of gene patents claim that genes should not be patentable subject matter because DNA sequences are at the core of humanity, which should not be controllable by individuals.<sup>19</sup> The USPTO has declined to rule on this issue, instead treating gene patenting as matter of statutory interpretation.<sup>20</sup> Therefore, attempts to end gene patents generally aim to overturn court precedent or to advocate new legislation.

A recent decision in the ACLU-supported case *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.* will help determine the future of gene patents in the United States. On March 29, 2010, United States District Court Judge Robert W. Sweet granted a summary judgment motion that invalidated patents on two genes linked to breast and ovarian cancer.<sup>21</sup> If upheld, this decision essentially eliminates patents covering all naturally occurring genes.<sup>22</sup>

## Restrictions on Gene Patenting in the United States

Concerns about gene patenting have been voiced in the United States for years. In 2007, a bill was introduced in Congress that would have essentially banned the patenting of DNA and DNA-related inventions. The Genomic Research and Accessibility Act (GRAA) would have radically altered United States patent law; GRAA would have banned patents on the human genome and all nucleotide sequences, including naturally occurring genes as well as synthetic DNA or RNA molecules.<sup>23</sup> GRAA was largely motivated by a perception that a proliferation of patents claiming human genes threatens to significantly impede biomedical research and block patient access to life-saving drugs and diagnostic testing services.<sup>24</sup> These fears have only increased in recent years. In spite of those concerns, GRAA did not garner much support. After its introduction and referral to subcommittees in early 2007, no movement has been reported, and the Act seems to have been abandoned.<sup>25</sup>

More recently, NIH-proposed guidelines recommend wide licensing of patented inventions to nonprofit researchers and public health agencies to promote patient health, emphasizing that exclusive licensing agreements have "detrimental short-term and long-term effects on both the quantity and quality of health care."<sup>26</sup> Following the filing of the present case, the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) for the Department of Health and Human Services (HHS) has produced a report on gene patents titled *Gene Patents and Licensing Practices and Their*

*Impact on Patient Access to Genetic Tests.*<sup>27</sup> The Committee proposes to exempt healthcare practitioners and researchers from infringement liability for gene patents. The recommendation, in its entirety:<sup>28</sup>

***1. Supporting the Creation of Exemptions from Infringement Liability***

The Secretary of Health and Human Services should support and work with the Secretary of Commerce to promote the following statutory changes:

A. The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes.

B. The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research.

With the report facing stiff opposition from the Biotechnology Industry Organization (BIO), legislative action may be a long time coming.<sup>29</sup> The BIO was joined by other prominent figures in its objection to the report's recommendations.<sup>30</sup> Senator Birch Bayh, co-author of the Bayh-Dole Act, Dr. Brian Stanton, a member of the SAGHS Task Force on Intellectual Property and Access to Genetic Testing, and Dr. Jon Soderstrom, the Managing Director of the Office of Cooperative Research at Yale University, all appeared in support at the BIO press conference. Former Indiana Senator Bayh maintained that the SAGHS recommendations would roll back the advances made



under Bayh-Dole and "would have a disastrous impact on the American economy."<sup>31</sup> Dr. Jim Davis, Executive Vice President, General Counsel and Secretary of Human Genome Sciences, Inc., stated that gene patents are the backbone of biotech innovation, leading to both diagnostic and therapeutic products.<sup>32</sup> Without gene patents, therapeutic drugs tailored for specific individuals would be more expensive and less protected by the patent system. Moreover, diagnostic testing such as that developed by Myriad would become open to the market at large.

Currently, biotechnology companies are heavily invested in their gene patents. Personalized medicine, in which drugs are tailored for specific genes, uses the protected commercialization of those targeted genes. Further, preventative care may depend on the development of more diagnostic tests such as the breast and ovarian cancer screenings at issue in this case. As one commentator states, if Myriad's loses the case in further litigation "the legal foundation for much of the drug business in the United States and, thus, the whole world would crumble."<sup>33</sup> Therefore, the biotechnology industry at large has a vested interest in any proposed legislation. As do consumers awaiting new drug developments. However, in spite of the variety of interests and the arguments made in favor of restricting gene patents, with such vocal dissent before proposed legislation even reaches Congress, it would be disingenuous to suggest that the issue will be resolved legislatively in the near future. With economic and public health concerns at war with each other, gene patents will probably fall by the wayside in the legislative agenda. In the meantime, it should be no surprise that researchers and opponents have already turned to litigation in an effort to eliminate gene patents.

### Does Gene Patenting Prevent Research?

As reform efforts continue, the fear associated with gene patenting should be addressed. Genes are an important component of disease research. Horrific diseases such as cystic fibrosis and sickle cell anemia are linked to specific genes within the human body.<sup>34</sup> Newborns are tested for myriad genetic disorders simply as a matter of public health with fairly minimal costs.<sup>35</sup> However, the relationship between genes and most diseases is not nearly as straightforward. Further research is required to understand gene interactions generally and drug targeting specifically.

The plaintiffs in the *Association for Molecular Pathology, et. al* case claim that "[a]llowing patents on genetic material imposes real and severe limits on scientific research, learning, and the free flow of information."<sup>36</sup> This argument is central to the ACLU's First Amendment concerns. In its brief, the ACLU argues that "the First Amendment limits the reach of intellectual property laws."<sup>37</sup> The ACLU labels six claims by which the defendants restrict the ability of researchers to observe and draw conclusions about patented genes, without confining that limitation to any particular methods of analyses. This prohibits the researchers from drawing any conclusions on patented BRCA genes, even if they used unpatented methods to study the genes.<sup>38</sup> For example, the ACLU cites Myriad's patent '999, which claims the act of looking at the patented BRCA1 gene. The ACLU also points to Myriad's patent '001, which covers the comparison of a naturally occurring mutation with a patient's blood sample to confirm the

presence of a gene mutation. "The claim does not specify or claim any particular method of obtaining or comparing the sequences; it simply covers the act of looking at the two sequences and concluding they are the same or different," the ACLU states in its brief.<sup>39</sup> Thus, the ACLU claims, researchers are prevented from conducting even the most basic studies of differences between the normal gene and the cancer-marker.

The precise scope of Myriad's patents, however, is unclear. A comprehensive search of legal databases conducted in 2007 attempted to identify every lawsuit that has ever been filed alleging infringement of a gene patent.<sup>40</sup> Many of the plaintiffs in the identified cases sued to restrict the infringer's commercial use of a patented product rather than to limit the infringer's research efforts. For instance, Myriad itself has filed suit in the past to enforce its BRCA patents. In a widely publicized case, Myriad sued the University of Pennsylvania for infringing its patents relating to the BRCA breast cancer genes.<sup>41</sup> Although suits filed against a university appear to discourage research and diagnostics, in this case the university was engaged in substantial commercialization of the patented technology.<sup>42</sup> The university was conducting BRCA genetic testing services for a purported \$1900 per test, in direct competition with Myriad's test. Myriad has been heavily criticized for purportedly asserting its patents against universities, but this appears to be the only lawsuit brought by Myriad against a university.<sup>43</sup>

Other examples of litigation include suits brought by gene patent owners trying to ensure that biomedical research continues without impediment. Specifically, a Ligand Pharmaceuticals Settlement Agreement explicitly granted two non-profit corporations named in the original suit a royalty-free, non-exclusive license to make and use the

technology for the purposes of basic research. Apparently, Ligand was only interested in using its patent to block commercial infringement by a direct competitor, not to block basic research.<sup>44</sup> The original suit named both the La Jolla Cancer Research Foundation and SRI International as defendants. Ligand's complaint alleged that these institutions were directly involved in the creation of Selectra, a private company engaged in a drug discovery program that directly competed with Ligand's business and that allegedly infringed Ligand's patents.<sup>45</sup> The parties settled the case, with the defendants agreeing to shut down the spin-off company and cease commercial use of the patented technology.<sup>46</sup>

The number of infringement lawsuits being filed by gene patent owners has been declining. Gene patent litigations peaked in 1997-1998, with a noticeable drop-off in recent years.<sup>47</sup> However, with increases in personalized medicine, including the diagnostic testing at issue in the current case, there may be a resurgence of gene patent litigation in the future.<sup>48</sup> Moreover, the number of cases does not accurately quantify the potential suppression of research. In addition to lawsuits, Myriad has asserted its patent rights through cease-and-desist letters. According to the original complaint, the company has enforced its BRCA1 and BRCA2 gene patent rights at least nine times, including against laboratories at Yale University.<sup>49</sup>

In the original complaint, one of the plaintiff's major concerns is that Myriad can assert its patent rights at any given moment, so researchers are reluctant to conduct research that may subject them to a lawsuit.<sup>50</sup> The complaint states that there are members of the Association for Molecular Pathology, the American College of Medical Genetics, the American Society for Clinical Pathology and the College of American

Pathologists who are “ready, willing, and able to engage in research and clinical practice involving the BRCA1 and BRCA2 genes if the patents are invalidated.”<sup>51</sup>

Furthermore, the chilling effect impacts more than direct research on BRCA1 and BRCA2. Since the interaction of genes within the human cell is poorly understood at best, researchers refrain from studying genes that *may* interact with the patented genes.<sup>52</sup> This is particularly concerning in light of recent advances in large-scale gene sequencing. Efforts to study how multiple genes can influence disease or cancer susceptibility are curtailed when some genes must be excluded due to gene patents.<sup>53</sup>

Additionally, gene patents are particularly powerful because they are impossible to design around.<sup>54</sup> Once a gene is patented, all non-licensed research related to that piece of DNA sequence ends until the expiration of the patent.<sup>55</sup> A researcher cannot create an alternative DNA sequence and still obtain meaningful clinical results. Thus, drug research that interacts with the genes cannot occur outside the company that owns the patents.

The number of genes thus restricted continues to increase. Between 1970 and 1979, only 123 DNA-based patents were granted.<sup>56</sup> The number increased to 16,057 between 1990 and 1999.<sup>57</sup> Since 2000, about 3,000 to 4,000 DNA-based patents have been granted each year.<sup>58</sup> In its report, the SACGHS noted that although researchers currently encounter only minor difficulties caused by human and gene patenting, “the complexity of the patent landscape is worrisome and may become ‘considerably more complex and burdensome over time.’”<sup>59</sup> As more genes are subject to patent protection, research options will contract. This limits drug innovation to commercial companies.

Whether directly enforced by lawsuits or cease-and-desist letters, or indirectly enforced by a chilling effect on research, the ACLU asserts that gene patents do not just have the potential to limit research, but that they do in fact limit research. While the number of infringement lawsuits may be declining, there is no evidence that this has encouraged researchers to start studying patented genes.

### Case History

On May 12, 2009, the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) filed a lawsuit against the U.S. Patent and Trademark Office (USPTO), Myriad Genetics (Myriad), and the University of Utah Research Foundation (UURF). The suit challenged two patents on the human genes BRCA1 and BRCA2 that the USPTO had granted to Myriad and UURF.<sup>60</sup> The complaint, filed in the U.S. District Court for the Southern District of New York, charged that the patents covering isolated two human genes associated with breast and ovarian cancer are unconstitutional and invalid. The plaintiffs argued that patents on genes violate the First Amendment and statutory patent law because genes are "products of nature" and therefore cannot be patented.<sup>61</sup> Because of the complaint's condemnation of the practice of gene patenting in general, the ACLU pointed out that the outcome in this case "could have far reaching effects beyond the patents on the BRCA genes."<sup>62</sup>

Mutations in the BRCA genes cause most cases of hereditary breast and ovarian cancers.<sup>63</sup> Women with a familial history of breast or ovarian cancer are often encouraged

to undergo genetic testing for BRCA gene mutations. The information provided allows earlier cancer detection and preventative care.<sup>64</sup> Myriad's BRCA1 and BRCA2 gene patents give the company the exclusive right to perform diagnostic tests and to prevent researchers from studying the genes unless they have permission from Myriad.<sup>65</sup> Myriad controls the market entirely, preventing patients from obtaining a second opinion or alternative testing.<sup>66</sup> These specific concerns as well as objections to gene patenting in general are the driving force behind the lawsuit.

The lawsuit was filed on behalf of researchers, genetic counselors, women patients, cancer survivors, breast cancer and women's health groups, and scientific associations representing 150,000 geneticists, pathologists, and laboratory professionals.<sup>67</sup> The complaint charged that the patents-in-suit stifle diagnostic testing and research that could lead to cures and limit women's options regarding their medical care. The ACLU claims that genes are products of nature and cannot be patented.<sup>68</sup> The ACLU also argues that patents on genes may hinder innovation because, under current law, Myriad and UURF would have the right to enforce patent protection against researchers studying or using these genes.<sup>69</sup>

Myriad has already faced resistance to the BRCA1 gene patent.<sup>70</sup> In May 2004, the European Patent Office revoked Myriad's patent on the BRCA1 gene.<sup>71</sup> The French challenge to the Myriad patent was prompted by the possibility of incomplete diagnostics. Specifically, Myriad forbade French doctors from undertaking BRCA1 testing directly, instead requiring that the tests be sent to Myriad's lab.<sup>72</sup> However, the sequencing technique used by Myriad Genetics failed to detect ten to twenty percent of

BRCA1 mutations.<sup>73</sup> Similarly, a study published in the Journal of the American Medical Association concluded that there was a twelve percent rate of false negatives for Myriad's genetic testing.<sup>74</sup> If diagnostic testing is conducted exclusively by one lab, that particular lab's standards govern the entire process. Rather than running the risk of inaccurate diagnostic tests, the European Patent Office revoked the patent entirely.

The ACLU has chosen the judicial system as a viable way to challenge gene patents. When the ACLU filed its Section 1983 action against the USPTO, Myriad, and the UURF, the complaint demanded that the BRCA gene patents be declared invalid as unpatentable under 35 USC § 101 "because human genes are products of nature, laws of nature and/or natural phenomena." The complaint specifically claims that in granting the gene patents, the USPTO violated Article I, Section 8, Clause 8 and the First Amendment of the Constitution.

To some commentators' surprise, the lawsuit continued after Judge Robert W. Sweet reviewed the Motions to Dismiss submitted by the defendants in an attempt to block the judicial system from revoking human gene patents.<sup>75</sup> The defendants brought these motions under Federal Rules of Civil Procedure 12(b)(1) (for lack of subject matter jurisdiction), 12(b)(2) (for lack of personal jurisdiction), and 12(b)(6) (for failure to state a claim).<sup>76</sup> Specifically, the defendants argued that there is a specialized regulatory system in place to govern patents and to redress violations of the Patent Act. Further, there is no statutory scheme providing a remedy for persons who complain about the constitutionality of patents issued by the USPTO and/or the policies and practices of the USPTO.<sup>77</sup> The defendants contended that there is simply no standing to sue and challenge



the USPTO or the patents it grants since “it is well established that third parties do not have standing to challenge the USPTO’s issuance of a patent.”<sup>78</sup> The personal jurisdiction challenge raised by the defendants questioned whether the UURF Directors were subject to the New York District Court’s jurisdiction.<sup>79</sup> Finally, the defendants argued that the plaintiffs failed to sufficiently state a claim pursuant to Fed. R. Civ. P. 12(b)(6).<sup>80</sup>

Judge Sweet denied the Motions to Dismiss on November 2, 2009, determining that under Fed. R. Civ. Pro. 12(b)(1) that the plaintiff’s claims provided adequate grounds for subject matter jurisdiction. He found that “[t]he novel circumstances presented by this action against the USPTO, the absence of any remedy provided in the Patent Act, and the important constitutional rights the Plaintiffs seek to vindicate establish subject matter jurisdiction over the Plaintiffs’ claim against the USPTO.”<sup>81</sup> The court further ruled that the plaintiffs have standing to sue the Patent Office for “constitutional violations” despite the lack of statutory remedy.<sup>82</sup>

On the failure to state a claim basis for defendants’ Motion to Dismiss, the district court found that the plaintiffs’ allegations of constitutional violations were sufficient, further holding that the complaint satisfied the stricter pleading requirements imposed by the Supreme Court in *Ashcroft v. Iqbal*.<sup>83</sup> The specific complaints meet the *Iqbal* requirements by alleging that the BRCA mutations are not inventions but “exist in nature,” and that the correlation between the presence of these mutations and an increased risk of cancer are “nothing more than a naturally-occurring phenomenon” and therefore unpatentable.<sup>84</sup> Noting that the standard is a liberal one and that a complaint should be

dismissed only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of its claims that would entitle it to the relief it seeks," the court found that the pleadings were enough for the plaintiffs to withstand defendants' Motion to Dismiss.<sup>85</sup>

After Judge Sweet denied the Motions to Dismiss, both plaintiffs and defendants filed motions requesting summary judgment. Oral arguments were heard on February 02, 2010. Judge Sweet cited the complexities of the case and the importance of the suit when he announced that he would wait to make a decision on whether a case should be decided, go to trial, or be dismissed.<sup>86</sup> Thus, his decision to grant summary judgment to the plaintiffs on March 29, 2010 was surprising.

### Patentability of Genes

In granting summary judgment, Judge Sweet held that Myriad's patents claiming "isolated DNA" do not qualify as patentable subject matter under 35 USC § 101. This decision is a striking departure from previous patentability standards.

Over two centuries ago, the framers of the U.S. Constitution codified incentives for technological innovation.<sup>87</sup> In return for a patent, the inventor must show that the invention satisfies a number of requirements, including a sufficient written description as well as utility, novelty, and nonobviousness.<sup>88</sup> Yet there are limits to what subject matter is considered patentable. For example, products of nature are not patentable.<sup>89</sup> One of the arguments brought forth by the ACLU is that genes are a product of nature, and therefore cannot be patented. "Patenting human genes is like patenting  $E=mc^2$ , blood, or air,"

argued ACLU attorney Chris Hansen.<sup>90</sup> Nevertheless, the scope of patentable subject matter is quite broad, encompassing “anything under the sun that is made by man.”<sup>91</sup>

DNA in the body is a product of nature and therefore not patentable.<sup>92</sup> Both plaintiffs and defendants recognized this basic point.<sup>93</sup> The patents at issue cover naturally occurring genes, but the defendants rely on the theory that the isolation of the BRCA genes — or the separation of the gene from the rest of the DNA— that is necessary to test and study genes makes them patentable.<sup>94</sup> “The novel compositions and methods resulted from the identification and isolation of two genes,”<sup>95</sup> rather than from DNA that exists in nature.

The case for patenting modified genes is fairly direct. In 1980, the United States Supreme Court's decision in *Diamond v. Chakrabarty* allowed the patenting of a living organism.<sup>96</sup> The Court determined that a living organism could be viewed as a “manufacture, or [a] composition of matter,” falling within two categories of patentable subject matter.<sup>97</sup> Moreover, congressional intent suggested that patentable subject matter should be broadly construed under Section 101 of the Patent Act.<sup>98</sup> Therefore, the Court concluded that a genetically modified organism is patentable subject matter because it is “a product of human ingenuity,” not a “hitherto unknown natural phenomenon.”<sup>99</sup> The Court in *Chakrabarty* found that the patentability of a living organism depended on whether the living thing was modified by a human, and thus refused to take an ethical stand on the issue.<sup>100</sup> Following this line of logic, although genes are regarded as natural parts of an organism, they

are patentable subject matter under Section 101 as long as the genes sought to be patented are modified by a researcher.

However, *Chakrabarty* alone does not justify the patenting of a naturally occurring gene. *Chakrabarty* explained that a claimed product must have “markedly different characteristics” from the natural phenomenon and that the use of the claimed product must be a result of the inventor’s effort, not “nature’s handiwork.”<sup>101</sup> The rationale for patenting a gene with its sequence unmodified is based on the 1970 *In re Bergstrom* decision, in which the Court of Customs and Patent Appeals held that a purified form of a compound was patentable even though its impure form was known to the public.<sup>102</sup> A compound merely discovered in nature would not be patentable, but because the pure form of the compound does not exist in nature, the purified compound is patentable subject matter.<sup>103</sup> Moreover, patentability is not destroyed even if the pure form of the compound has the same function as the compound found in nature.<sup>104</sup> Although genes exist in nature as part of DNA, they do not exist in their pure form. An isolated and identified gene would then be patentable under Section 101 without its sequence being modified by a researcher. The conclusion that an isolated and purified gene is patentable was accepted by the Federal Circuit.<sup>105</sup>

According to the defendants, under *In re Bergstrom*, Myriad’s isolation and purification of the gene qualify the gene for patentability. The USPTO has considered this argument before and agrees with the defendants. Following criticism that the USPTO was too liberal in approving gene patents,<sup>106</sup> internal review led to the conclusion that the agency was bound by policy and case law to reject arguments that genes were

products of nature and thus unpatentable.<sup>107</sup> In granting summary judgment, Judge Sweets disagreed with the USPTO and moved away from Federal Circuit precedent.

### Summary Judgment Decision

It is rare for a plaintiff to succeed in a summary judgment motion because the plaintiff bears the burden of proof.<sup>108</sup> In granting summary judgment, Judge Sweet determined that there were no issues of material fact to be decided. Judge Sweet used a straightforward application of patent law to invalidate the patents.

The decision divided the patent claims into two groups: patents claiming gene sequences that had been isolated from DNA and patents claiming methods for analyzing genes in order to identify breast or ovarian cancer markers. Both sets of claims were rejected under Section 101 of the Patent Act.

#### *Isolated Genes*

Judge Sweet held that isolated genes are insufficiently different from naturally occurring DNA and thus are ineligible for patent protection. In so holding, the court emphasized the separation between patentable subject matter and other sections of the Patent Act.<sup>109</sup> Just because a discovery is new or useful doesn't make it patentable. Cases cited by Myriad were distinguished as addressing novelty and obviousness concerns, not the question of patentable subject matter.<sup>110</sup> There is a separate determination for patentable subject matter; in this case, whether the genes are products of nature or

inventions. In *Chakrabarty*, the court specifically stated that “the laws of nature, physical phenomena, and abstract ideas have been held not patentable.”<sup>111</sup>

Myriad asserted that the isolated genes were not simply products of nature, arguing that the isolated genes were “substantially separated from other cellular components which naturally accompany a native human sequence [such as] human genome sequences and proteins.”<sup>112</sup> The defendants argued that the purification of naturally occurring BRCA genes renders them patentable, especially in light of that ‘substantial separation.’<sup>113</sup>

Tracing a line of cases from the 1874 decision in *American Wood-Paper Co. v. Fibre Disintegrating Co.* to *Chakrabarty* in 1980, the court concluded that “purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess ‘markedly different characteristics’ in order to satisfy the requirements of §101.”<sup>114</sup> The question is whether the BRCA genes meet this standard.

In the decision, the court found that Myriad’s isolated genes failed the test and were nothing more than products of nature. The function of a gene does not vary from its function *in vivo* when it is isolated in a laboratory setting. Instead, Judge Sweet determined that “DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA’s existence in an ‘isolated’ form alters neither this fundamental quality as it exists in the body nor the information it encodes.”<sup>115</sup> The critical aspect of DNA is that it carries information; it does not operate simply as a chemical. Thus, the

isolated BRCA genes fail to demonstrate markedly different characteristics from BRCA genes in the human body.

The court's focus on genes as something more than merely chemicals is a substantial departure from precedent.<sup>116</sup> With this decision, genes now fall outside of the *In re Bergstrom* holding that simply requires the purification of naturally occurring chemicals in order for those chemicals to be patentable. This distinction demolishes the foundation of gene patenting. Any purified or isolated version of a naturally occurring gene would fail the test for patentability.

#### *Methods for Gene Analysis*

In the second part of its analysis, the court applied the “machine or transformation” test from the Federal Circuit's decision in *In re Bilski* to the method claims in the patents.<sup>117</sup> In applying this test, Judge Sweet held that the patent claims were not linked to any machine, nor was there any tangible transformation. There was no restriction on the methods used to compare the genes and no further actions described beyond analyzing the genes. The method claims that required comparison between DNA sequences were abstract mental processes and therefore unpatentable subject matter.<sup>118</sup>

Even if the patent claims had explained how to isolate and sequence the DNA, this would merely be information gathering and would not have saved the patent from being rejected.<sup>119</sup> In spite of the physical transformations required to isolate DNA, Judge Sweet determined that the claims would “would still fail the ‘machine or transformation’ test under § 101 for subject matter patentability” under *Bilski*.<sup>120</sup>

Although raised by the ACLU and cited in Judge Sweet's decision on the Motions to Dismiss, the constitutional arguments were not addressed in the decision granting summary judgment. Judge Sweet applied the doctrine of constitutional avoidance to refrain from unnecessarily ruling on constitutional questions.<sup>121</sup> Since the patents were invalidated on other grounds and the plaintiffs gained the requested relief, the constitutional claims against the USPTO were dismissed without prejudice.<sup>122</sup>

The summary judgment decision invalidated claims for both isolated genes and methods for gene analysis, leaving gene patenting in a very precarious position in the New York District Court.

### Implications of the Decision

The immediate effect of the decision should not be overstated. Myriad will certainly appeal the summary judgment to the Federal Circuit.<sup>123</sup> Judge Sweet's decision will only apply to the patents at issue in the present case and will not be binding on any other court.<sup>124</sup> Thus the vast majority of the pharmaceutical industry can continue developing drugs based on gene patents without immediate fear that their work will be unprotected by United States law. However, the decision does present an excellent test case for the Federal Circuit and perhaps the Supreme Court to address gene patentability. Should the Federal Circuit uphold the ruling, it will be binding on all federal courts except the Supreme Court.<sup>125</sup> A ruling that upheld Judge Sweet's decision would force changes in the biotechnology industry.



Judge Sweet's ruling has an effect beyond its legal decision. As mentioned above, attempts to restrict gene patenting through the legislature have been unsuccessful. Thus, any court moving on this issue can expect media attention. Gene patenting was at the heart of this case, and the decision unequivocally invalidated patents on naturally occurring genes. The simplicity of this fact is evidenced by the articles that shortly followed the summary judgment decision. "Judge Invalidates Human Gene Patent," "Judge Nullifies Gene Patents," and "The End of Gene Patenting?" are just a few of the articles and blog postings published in the wake of the decision.<sup>126</sup>

Additionally, the plaintiffs chose an excellent case from a policy perspective. Many women are at risk for breast and ovarian cancer and see genetic testing as one of the few preventative measures available.<sup>127</sup> The plaintiffs are universities, professional organizations and cancer patients who could not afford to pay Myriad's monopoly price on diagnostics: quintessentially sympathetic figures. Should the Federal Circuit overturn the decision, it will be seen not just as a legal or scientific matter, but also as a social concern. The failure of the courts to protect the interests of sympathetic plaintiffs may spur popular support for legislative reform in a way that other patent cases would not.

On the research front, this decision may shift the biotechnology industry away from gene isolation. Bryan Roberts, a prominent Silicon Valley venture capitalist, stated that "[t]he government is going to become the funder for content discovery because it's going to be very hard to justify it outside of academia."<sup>128</sup> However, the decision could also spur the development of synthetic genes for testing and shift the focus away from naturally occurring genes.<sup>129</sup> This level of creativity is particularly important during a

time when “medicine [is] becoming more personalized, with genetic tests used not only to diagnose diseases but to determine which medicine [is] best for which patient.”<sup>130</sup>

A federal court decision that invalidates specific gene patents on Section 101 grounds calls into question all gene patents. If DNA is a product of nature and an isolated gene does not possess markedly different characteristics, then the isolated gene is not patentable according to Judge Sweet’s analysis. Even if the Federal Circuit overturns the decision, the outcome of the case has placed gene patents under far more public scrutiny than has existed in the past.

As an industry, biotech companies must decide how to proceed with their business models. If the Biotechnology Industry Organization is correct and this fundamentally changes how pharmaceutical research is conducted within the United States, companies cannot be complacent. While the Federal Court may overturn the decision entirely or (more likely) simply alter the scope of gene patents, companies cannot afford to depend on this outcome.

Certainly, research allocation must adjust if gene research protections change. Even if the courts strike down gene patents generally, there are ways for companies to pursue innovation while maintaining patent protections. As mentioned above, synthetic genes are still patentable under Judge Sweet’s decision, so would still be protected by patent laws. But even natural genes are not *entirely* outside the scope of protection during drug development. For instance, the application of a gene function, as long as the application is a non-obvious application of knowledge of a gene function, may be patentable.<sup>131</sup> This would hold true even if gene patents are eliminated by the courts or

legislatively. The industry is working through organizations such as BIO to prevent changes to the laws, but individual companies should protect their own investments by determining how best to structure future R&D without losing the protections offered by patent law.

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<sup>1</sup> Brand name sales totaled \$ 220.6 billion, while generic sales accounted for the remaining \$ 54.1 billion. Generic Pharmaceutical Association, *Statistics*, available at <http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm>.

<sup>2</sup> PHARMACEUTICAL RESEARCH AND MANUFACTURES OF AMERICA (PHRMA), What Goes Into The Costs Of Prescription Drugs...And Other Questions About Your Medicine 10 (2005), [http://www.phrma.org/files/Cost\\_of\\_Perscription\\_Drugs.pdf](http://www.phrma.org/files/Cost_of_Perscription_Drugs.pdf).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> THE BIOTECHNOLOGY INDUSTRY ORGANIZATION, Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing, 3 (2007) <http://www.bio.org/ip/action/20071030.pdf>.

<sup>6</sup> *Id.*

<sup>7</sup> *See id.* at 4.

<sup>8</sup> Nick Timiraos, *Businesses Battle Over Patent Laws*, WALL STREET JOURNAL, June 9, 2007 at A7.

<sup>9</sup> *Id.* (Clinical trials, FDA approval, etc. delay commercialization of drugs).

<sup>10</sup> *See* Stacy Lawrence, *Pipelines Turn to Biotech*, 25 NATURE BIOTECHNOLOGY 1342, 1342 (2007).

<sup>11</sup> Gregory C. Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents*, 15 Rich. J.L. & Tech. 1 (Fall 2008).

<sup>12</sup> n10 *See* Saurabh Aggarwal, *What's Fueling the Biotech Engine?*, 25 NATURE BIOTECHNOLOGY 1097, 1097 (2007).

<sup>13</sup> *See* Gary Walsh, *Biopharmaceutical Benchmarks 2006*, 24 NATURE BIOTECHNOLOGY 769, 775 fig.3 (2006) (providing an update on new arrivals to the biopharmaceutical market).

<sup>14</sup> *See* Stacy Lawrence, *Pipelines Turn to Biotech*, 25 NATURE BIOTECHNOLOGY 1342, 1342 (2007).

<sup>15</sup> *See* Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics Under Existing Law and Proposed Reforms to the Law*, 62 FOOD & DRUG L.J. 77, 78-79 (2007) (providing a brief description of traditional drugs in comparison to biologic drugs).

<sup>16</sup> Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 Sci. 239, 239 (2005).

<sup>17</sup> Andrew W. Torrance, *After the Gene Rush*, BIO-IT World, Nov. 2002, at 80.

<sup>18</sup> Editorial, *Leader: Whose Life is it Anyway?: The Knowledge Economy Should Be for All*, Guardian (Manchester, U.K.), Nov. 15, 2000, at 23, <http://www.guardian.co.uk/science/2000/nov/15/genetics.guardianleaders>.

<sup>19</sup> USPTO Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

<sup>20</sup> *See id.* at 1093–94.

<sup>21</sup> John Schwartz and Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, March 29, 2010, at B1 available at <http://www.nytimes.com/2010/03/30/business/30gene.html?hpw>.

<sup>22</sup> *See* Court: Essentially All Gene Patents Are Invalid, <http://www.patentlyo.com/patent/2010/03/court-essentially-all-gene-patents-are-invalid.html> (Mar. 30, 2010, 7:17 EST).

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- <sup>23</sup> H.R. 977, 110th Cong. (2007). “Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.” *Id.*
- <sup>24</sup> H.R. 977, 110th Cong. (2007); *see* Christopher M. Holman, The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation, 76 U. Mo.-Kan. City L. Rev. 295 (2007).
- <sup>25</sup> GovTrack.us, <http://www.govtrack.us/congress/bill.xpd?bill=h110-977> (last visited on Dec. 2, 2009). Issues regarding the patentability of biological molecules are not mentioned in the latest efforts to reform the Patent Act. S. 515, 111th Cong. (2009); H.R. 1260, 111th Cong. (2009).
- <sup>26</sup> David Malakoff, NIH Roils Academe with Advice on Licensing DNA Patents, 303 Science 1757, 1758 (2004) (quoting NIH draft guidelines).
- <sup>27</sup> *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, draft report, available at <http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%202-5-2010.pdf>.
- <sup>28</sup> *Id.* at 99.
- <sup>29</sup> Posting of Donald Zuhn to Patent Docs, <http://www.patentdocs.org/2010/02/bio-comes-out-swinging-against-sacghs-report.html> (Feb. 04, 2010, 23:55 EST).
- <sup>30</sup> *Id.*
- <sup>31</sup> *Id.*
- <sup>32</sup> *Id.*
- <sup>33</sup> Do DNA patents spur science or stifle it? Both - Breaking Bioethics- msnbc.com, <http://www.msnbc.msn.com/id/30719222> (last visited Apr. 04, 2010).
- <sup>34</sup> WHAT ARE GENETIC DISORDERS? What are Genetic Disorders?, <http://learn.genetics.utah.edu/content/disorders/whataregd/> (last visited Apr. 3, 2010).
- <sup>35</sup> NEWBORN GENETIC SCREENING Newborn Genetic Screening, <http://learn.genetics.utah.edu/content/health/ngs/> (last visited Apr. 4, 2010). Estimated costs to patients ranges from less than \$15 to nearly \$60.
- <sup>36</sup> Press Release, American Civil Liberties Union, ACLU and PUBPAT Argue Today That Patents on Breast Cancer Genes Are Unconstitutional and Invalid (Feb. 02, 2010), <http://www.aclu.org/free-speech-womens-rights/aclu-and-pubpat-argue-today-patents-breast-cancer-genes-are-unconstitution>.
- <sup>37</sup> Pls.’ Mem. of Law in Supp. of Mot. for Summ. J. at 32, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, No. 62 (S.D.N.Y. Jan. 20, 2010) (1:09-cv-04515-RWS).
- <sup>38</sup> *Id.*
- <sup>39</sup> Pls.’ Mem. of Law in Supp. of Mot. for Summ. J. at 4, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, No. 62 (S.D.N.Y. Jan. 20, 2010) (1:09-cv-04515-RWS).
- <sup>40</sup> Christopher M. Holman, *Learning from Litigation: What Can Lawsuits Teach Us about the Role of Human Gene Patents in Research and Innovation*, 18-WTR Kan. J.L. & Pub 215, 217 (2009).
- <sup>41</sup> *Myriad Genetics, Inc. v. Univ. of Pa.*, 2:98-cv-0829-S (D. Utah Nov. 19, 1998).
- <sup>42</sup> *Supra* note 22 at 260.
- <sup>43</sup> *Id.*
- <sup>44</sup> Ligand Pharms., Inc., Quarterly Report, Settlement Agreement, License and Mutual General Release (Form 10-Q), at B-14 (Mar. 31, 1997).
- <sup>45</sup> *Id.* at B-2.
- <sup>46</sup> *Id.* at B-6.
- <sup>47</sup> *Supra* note 40 at 219.
- <sup>48</sup> *See id.* at 263.
- <sup>49</sup> Complaint at ¶ 49, *Association for Molecular Pathology*, No. 09 Civ. 4515, (S.D.N.Y. Mar. 29, 2010).
- <sup>50</sup> *Id.* at ¶ 97–98.
- <sup>51</sup> Compl. *supra* note 49 at ¶ 7–10.
- <sup>52</sup> *Id.*
- <sup>53</sup> *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, No. 09 Civ. 4515, slip op. at 74–75 (S.D.N.Y. Mar. 29, 2010).

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<sup>54</sup> Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 Tex. Intell. Prop. L.J. 221, 257 (2003).

<sup>55</sup> See Ying Pan, *A Post-KSR Consideration of Gene Patents: The "Obvious To Try" Standard Limits the Patentability of Genes*, 11 93 Marq. L. Rev. 285, 295 (2009).

<sup>56</sup> DPD: About the DNA Patent Database, <http://dnapatents.georgetown.edu/aboutdpd.htm> (last visited Mar. 4, 2010). "The DPD is a core of Duke University's Center for Excellence in ELSI Research ...." *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> SACGHS *supra* note 12 at 1 (quoting NRC). (2006). *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*. Washington, DC: National Academies Press.

<sup>60</sup> Press Release, American Civil Liberties Union, ACLU Challenges Patents On Breast Cancer Genes: BRCA (Febuary 17, 2010), <http://www.aclu.org/free-speech-womens-rights/aclu-challenges-patents-breast-cancer-genes-0>. The patents named in the suit include: patent 5,747,282 (the "'282 patent"), 5,837,492 (the "'492 patent"); patent 5,693,473 (the "'473 patent"), patent 5,709,999 (the "'999 patent"), patent 5,710,001 (the "'001 patent"), patent 5,753,441 (the "'441 patent"), patent 6,033,857 (the "'857 patent"). See *supra* note 21 at 33.

<sup>61</sup> *Id.*

<sup>62</sup> *Supra* note 36.

<sup>63</sup> *Supra* note 18.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Supra* note 21.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 Yale J. Health Pol'y L. & Ethics 403, 403 (2005).

<sup>71</sup> Press Release, Eur. Patent Office, "Myriad/Breast Cancer" Patent Revoked After Public Hearing (May 18, 2004), <http://www.epo.org/about-us/press/releases/archive/2004/18052004.html>. Decision Revoking the European Patent (Art. 102(1), (3) EPC) (Eur. Pat. Office May 17, 2004) (revoking European Patent No. 0699754) [hereinafter Revocation Decision].

<sup>72</sup> Press Release, Institut Curie, Assistance Publique-Hopitaux de Paris, & Institut Gustave-Roussy, Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene 5 (Sept. 26, 2002), [http://www.curie.fr/upload/presse/3oppmyriad\\_sept02\\_fr.pdf](http://www.curie.fr/upload/presse/3oppmyriad_sept02_fr.pdf).

<sup>73</sup> *Id.* at 5. For an example of a mutation that Myriad missed, see Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. Med. Genetics 388, 388 (2001).

<sup>74</sup> See Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al., No. 09 Civ. 4515, slip op. at 64 (S.D.N.Y. Mar. 29, 2010).

<sup>75</sup> Posting of Gene Quinn to IPWatchdog, <http://www.ipwatchdog.com/2009/11/02/district-court-rules-aclu-gene-patent-challenge-may-proceed/id=7115/> (Nov. 02, 2009, 11:56 EST). Describing Judge Sweet's ruling as "perhaps the worst opinion I have ever read from any federal court."

<sup>76</sup> Fed. R. Civ. P. 12(b)(1, 2, 6).

<sup>77</sup> See Block v. Cmty. Nutrition Inst., 467 U.S. 340, 349 (1984).

<sup>78</sup> Mot. to Dismiss, Nov. 02, 2009 at 45.

<sup>79</sup> *Id.* at 40–41.

<sup>80</sup> *Id.* at 37–38.

<sup>81</sup> *Id.* at 46.

<sup>82</sup> *Id.* at 46.

<sup>83</sup> *Id.* at 82.

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<sup>84</sup> *Supra* note 49 at ¶ 34, 46, 51, 55–60.

<sup>85</sup> *Supra* note 25 at 81–82.

<sup>86</sup> Matt Jones, *Myriad, ACLU Clash over Gene IP in NY Court*, GENOME WEB, Feb. 2, 2010, <http://www.genomeweb.com/dxpgx/myriad-aclu-clash-over-gene-ip-ny-court>.

<sup>87</sup> The Constitution gives Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, 8, cl. 8.

<sup>88</sup> See 35 U.S.C. §100-05 (2000).

<sup>89</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

<sup>90</sup> *Supra* note 36.

<sup>91</sup> *Id.* (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

<sup>92</sup> John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents, Part I*, 85 J. Pat. & Trademark Off. Soc'y 301, 305 (2003).

<sup>93</sup> Memorandum of Law (1) In Further Support of Plaintiffs' Motion for Summary Judgment Against All Defendants and (2) In Opposition to The Myriad Defendants' Motion for Summary Judgment and (3) In Opposition to Defendant United States Patent and Trademark Office's Motion for Judgment on the Pleadings at 4, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, No. 219 (S.D.N.Y. Jan. 20, 2010) (1:09-cv-04515-RWS).

<sup>94</sup> Myriad Defs' Mem. of Law (1) In Supp. of Their Mot. for Summ. J. and (2) In Opp'n to Pls' Mot. for Summ. J. at 7, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, No. 153 (S.D.N.Y. Jan. 20, 2010) (1:09-cv-04515-RWS).

<sup>95</sup> *Id.* at 8.

<sup>96</sup> *Supra* note 89 at 309.

<sup>97</sup> *Id.* at 308.

<sup>98</sup> *Id.* at 309.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 316–18.

<sup>101</sup> *Id.* at 309–310.

<sup>102</sup> *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970).

<sup>103</sup> *Id.* at 1401.

<sup>104</sup> *Id.* at 1402.

<sup>105</sup> See *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (holding that "[a] gene is a chemical compound, albeit a complex one").

<sup>106</sup> Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 Stan. L. & Pol'y Rev. 417, 420–21 (2003).

<sup>107</sup> *Id.* at 439.

<sup>108</sup> Posting of John Conley and Dan Vorhaus to Genomics Law Report, <http://www.genomicslawreport.com/index.php/2010/03/30/pigs-fly-federal-court-invalidates-myriads-patent-claims/> (Mar. 30, 2010).

<sup>109</sup> See *supra* note 53 at 115.

<sup>110</sup> *Id.* at 115–118.

<sup>111</sup> *Chakrabarty*, 447 U.S. at 309.

<sup>112</sup> *Supra* note 53 at 92.

<sup>113</sup> *Id.* at 115.

<sup>114</sup> *Id.* at 110–121.

<sup>115</sup> *Id.* at 3–4.

<sup>116</sup> See *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (holding that "[a] gene is a chemical compound, albeit a complex one").

<sup>117</sup> *In re Bilski* 545 F.3d 943, 953 (Fed. Cir. 2008).

<sup>118</sup> *Supra* note 53 at 4 (S.D.N.Y. Mar. 29, 2010).

<sup>119</sup> *Id.* at 146–147.

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<sup>120</sup> *Id.* at 147.

<sup>121</sup> *Id.* at 149–150.

<sup>122</sup> *Id.* at 151.

<sup>123</sup> Susan Decker and Thom Weidlich, *Myriad Loses Ruling Over Breast Cancer-Gene Patents (Update3)*, (March 29, 2010), <http://www.businessweek.com/news/2010-03-29/myriad-loses-ruling-over-breast-cancer-gene-patents-update1-.html>.

<sup>124</sup> Posting of John Conley and Dan Vorhaus to Genomics Law Report, <http://www.genomicslawreport.com/index.php/2010/03/30/pigs-fly-federal-court-invalidates-myriads-patent-claims/> (Mar. 30, 2010).

<sup>125</sup> *Id.*

<sup>126</sup> John Schwartz and Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, March 29, 2010, at B1 available at <http://www.nytimes.com/2010/03/30/business/30gene.html?hpw>; David Kravets, *Judge Nullifies Gene Patents*, (Mar. 29, 2010), <http://www.wired.com/threatlevel/2010/03/judge-nullifies-gene-patents/>; Posting of Mark Henderson to TimesOnline, <http://timesonline.typepad.com/science/2010/03/the-end-of-gene-patenting.html> (Mar. 30, 2010).

<sup>127</sup> See John Schwartz, *Cancer Patients Challenge the Patenting of a Gene*, N.Y. TIMES, May 12, 2009, at A16, available at [http://www.nytimes.com/2009/05/13/health/13patent.html?\\_r=1](http://www.nytimes.com/2009/05/13/health/13patent.html?_r=1).

<sup>128</sup> *Supra* note 21.

<sup>129</sup> Susan Decker and Thom Weidlich, *Myriad Loses Ruling Over Breast Cancer-Gene Patents (Update3)*, (March 29, 2010), <http://www.businessweek.com/news/2010-03-29/myriad-loses-ruling-over-breast-cancer-gene-patents-update1-.html>.

<sup>130</sup> *Supra* note 21.

<sup>131</sup> Allen K. Yu, *Why it Might Be Time to Eliminate Genomic Patents, Together with the Natural Extracts Doctrine Supporting such Patents*, 47 IDEA 659, 752-753 (2007).